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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	LESLIE A. ROYDS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09Feb09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 30-34 are presented for examination.

Applicant's Amendment and Information Disclosure Statement (IDS) filed February 9, 2009 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08(a-b) (two pages total), the Examiner has considered the cited reference.

Claims 1-11 and 30-34 remain pending and under examination. Claims 33-34 are newly added. Claims 1 and 7 are amended.

Applicant's arguments, filed February 9, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 30-32 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.2-4 of the previous Office Action dated November 7, 2008, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that support for this step of the method can be found at p.1, l.3-6 and p.2, l.17-21, wherein the specification discloses that the instant methods are directed to the treatment of obesity and conditions of overweight in mammals, especially the pediatric population. Applicant again relies upon Merriam-Webster to define the term "treat" as "caring for or dealing with medically or surgically, such as to treat a disease" to show that, in order to care for or deal with a condition such as obesity and conditions of overweight, the obesity and the conditions of overweight must be identified. Still further, Applicant submits that the specification describes suitable means for identifying an obese or overweight mammal and references the disclosure of body mass index (BMI) in the specification as overweight in between 25 and 29.9 or obese if greater than 30. Applicant insists that, in order to treat a condition of obesity or overweight in a mammal, there must be some recognition of the condition. Applicant submits that, even in the examples provided by the Office at p.3, there is inherently recognition that the mammal is obese or overweight. Applicant further asserts that methods of identifying an overweight or obese patient is subject matter that is conventional or well known to the skilled artisan and does not need to be described in order to satisfy the written description requirement.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, as before, Applicant's position appears to be grounded in the belief that the very disclosure of the term "treating" implies an inherent identification step and, thus, provides support for this limitation. However, the administration of the instantly claimed polyunsaturated fatty acid composition to an overweight or obese mammal does not necessarily imply that such an overweight or obese mammal was, in fact, particularly identified as such prior to administration. In other words, it is understood that the "identification" step as claimed would include, for lack of a *specific* definition by Applicant, physiologic tests and/or measurements of height and weight to determine, e.g., body mass index,

percentage body fat, etc. However, such a step of identifying a patient of this type is not necessarily implied as part of Applicant's originally disclosed and claimed method because it would be possible to administer the claimed composition to either a previously identified obese or overweight mammal (i.e., one that has undergone identification prior to the contemplation of executing Applicant's instantly claimed method) or one that is overtly and obviously overweight or obese such that a specific identification step (i.e., of performing such medical assessments for verification) would not be required. For these reasons, and again in view of the lack of a specific teaching, suggestion or disclosure as to the identification of an overweight or obese mammal prior to administration of the instantly claimed polyunsaturated fatty acid composition, Applicant's limitation directed to the identification of an overweigh or obese mammal is, as before, not adequately supported, either explicitly *or implicitly*, by the specification and claims as originally filed.

Secondly, it is again noted that the instant specification discloses a body mass index (BMI) parameter used to define the degree of overweight or obesity. However, even if, *arguendo*, such disclosure was sufficient to provide disclosure of a patient identification step (which the Examiner does not concede), the specific disclosure of a *single* parameter determination step in order to identify an overweight or obese patient fails to be supportive of the broader concept of identifying an overweight or obese patient via *any* identification means. In other words, the disclosure of a specific manner of identifying a patient (which, again, the Examiner does not concede that the reference to BMI in the instant specification constitutes an implicit disclosure of a step of patient identification) fails to provide adequate written support for the generic concept of "identifying" an obese or overweight mammal using any possible identification means. This is, therefore, and will remain, a clear broadening of the subject matter disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and Applicant’s citation of specific portions of the

instant specification do not remedy this lack of description of the same. For these reasons, the claims continue to fail to meet the statutory requirements of 35 U.S.C. 112, first paragraph.

To clarify, even if, *arguendo*, the disclosure of BMI was understood as an implicit teaching of a patient identification step as claimed (which the Examiner does not concede), the disclosure of a single method of identification would still fail to provide adequate written support to then broadly claim the use of *any* method of identifying an obese or overweight mammal. This is because the disclosure of a single species fails to demonstrate that Applicant was in possession (and contemplated the use) of any method of identification falling within the full scope of the claimed genus. This is because Applicant cannot logically be in possession of that which he has yet to identify and/or had yet to describe was actually contemplated at the time of the invention.

Lastly, the allegation that other methods of identifying obese or overweight patients are conventional and well known to one of ordinary skill in the art is unpersuasive. What may have been "obvious" or "within the skill of the artisan" is not the standard to which written description is held. Any aspect of an invention is supported by adequate written description when it is clearly shown that a concept was within Applicant's possession at the time of the invention. As stated in MPEP §2163, "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention." In the instant case, the specification does not adequately describe this identification step for the reasons discussed *supra*. In addition, the idea that one of ordinary skill in the art would have understood that such a step would have necessarily been implied without adequately describing such a step is insufficient to demonstrate that Applicant contemplated, and was in possession of, *any* method of identification as instantly claimed *at the time of the invention*.

For the reasons provided *supra*, and those previously made of record at p.2-4 of the Office Action dated November 7, 2008, rejection of claims 1-11 and 30-32 remains proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135), each already of record, for the reasons of record set forth at p.6-11 of the previous Office Action dated November 7, 2008, of which said reasons are herein incorporated by reference, in view of newly cited Bren ("Losing Weight: Start by Counting Calories", *FDA Consumer Magazine*, 2002 Jan-Feb; Pub. No. FDA 04-1303C, p.1-6).

Newly amended claim 1 and newly added claim 33 (directed to substantially identical subject matter as instant claim 1 but for the fact that newly added claim 33 does not require an identification step)

now require that the appetite of the obese or overweight mammal being treated needs to be decreased. The instant claims remain properly included in the present rejection because Bren teaches that, to combat obesity in overweight or obese patients, one should maintain a healthy diet and weight and to make smart choices about their diet (p.1, para.4-5), including reduced calorie consumption via cutting back on the number of calories eaten by eating smaller amounts of food and choosing foods lower in calories (p.4, para.1-3). Thus, the teaching of an obese human patient as in Visser et al. is also clearly a mammal who needs a decrease or reduction in appetite to maintain a healthy and/or normal weight, as evidenced by Bren, which meets the requirements of Applicant's instant claims.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the cited references fail to provide any apparent reason to combine or modify the references to arrive at the claimed limitation directed to enteral administration at the time prior to or in conjunction with an appetite-impacting stimulus for the purpose of decreasing the appetite of the mammal and treat obesity or conditions of overweight. Applicant alleges that the "appetite-impacting stimulus" is defined in the instant specification as a stressor or stimulus that has the effect of increasing food intake and gives examples of irregular meals, sleep deprivation, and parental expectations to excel in school and/or sports, and *is not* the "general condition which is present in an individual at all times, as suggested by the Office". (p.18, Remarks) Applicant again insists that there is no mention anywhere in the cited references that the formulation of Phinney et al. will affect the appetite of obese or overweight mammals whose appetite needs to be decreased. Still further, Applicant alleges that claim 1 requires the appetite of the mammal to be one that needs to be decreased and states that the Office is in agreement that not all obese or overweight mammals have an appetite that needs to be decreased.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's argument that the cited references fail to enteral administration at a time prior to or in conjunction with an appetite-impacting stimulus to said mammal an amount of long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal is unpersuasive for the following reasons: (1) Phinney et al. explicitly teaches the administration of DHA- containing formulation orally (i.e., "enterally" as in instant claim 1 and 33), such as via capsules, tablets, pills, soft gel-caps, powders, solutions, dispersions or liquids (p.23, 1.34-36), (2) Phinney et al. also explicitly teaches the administration of DHA in an exemplary amount of 10-10,000 mg (p.27, 1.23-31), which meets Applicant's defined amount of instant claim 6 as an amount of the active long-chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal and (3) the administration as disclosed by Phinney et al. meets the limitation directed to administration "at a time prior to or in conjunction with an appetite-impacting stimulus" because the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood such that growth of the human body in any of these three stages (i.e., infancy, adolescence or adulthood) would necessarily be present at any time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth and, therefore, in view of the fact that Applicant has only provided an exemplary list of stimuli that constitute the "appetite-impacting stimulus" as instantly claimed, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary. Accordingly, Applicant's allegation that the reference to Phinney et al. fails to meet these limitations of the instant claims is clearly without merit.

Applicant continues to stress that the conditions of administration as disclosed in Phinney et al. do not meet the requirement of administering “prior to or in conjunction with an appetite-impacting stimulus”. This is, and will remain, unpersuasive because Applicant has provided only an *exemplary definition of what constitutes such appetite-impacting stimuli as instantly claimed.* Thus, while a period

of growth as described *supra* may not fall within those exemplary stressors that Applicant has listed in the instant specification as constituting an "appetite-impacting stimulus", the stimulus as instantly claimed is not limited to the specific conditions described in the specification and Applicant has failed to provide any evidence that the interpretation provided by the Office (i.e., that the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood such that growth of the human body in any of these three stages would necessarily be present at any time the composition was administered and would be reasonably considered a period of stress on the human body that requires increased food intake and proper nutrition and health in order to permit such growth and, thus, is an "appetite-impacting stimulus") is unreasonable and excluded by the instant claims. In the absence of such evidence to support Applicant's allegations, it is maintained that this interpretation is reasonable and consistent with the art and, therefore, the conditions of administration as disclosed by Phinney et al. meet Applicant's claimed limitation directed to administration "prior to or in conjunction with an appetite-impacting stimulus", absent factual evidence to the contrary.

Secondly, Applicant continues to insist that the cited references do not teach or suggest that the formulation of Phinney et al., when administered, will affect the appetite of obese or overweight mammals whose appetite needs to be decreased. This is again, as before, unpersuasive. Though it is acknowledged that Phinney et al. does not explicitly teach the reduction in appetite in an obese or overweight mammal or the identification of an overweight or obese mammal, Phinney et al. provides a clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, e.g., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual

evidence demonstrating that a subpopulation of such patients suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the intent to reduce C-reactive protein and with the reasonable expectation of the same (or at least substantially equivalent) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Moreover, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

Thirdly, Applicant alleges that claim 1 requires the appetite of the mammal to be one that needs to be decreased and states that the Office is in agreement that not all obese or overweight mammals have an appetite that needs to be decreased. This is also unpersuasive. The newly cited reference to Bren teaches that, to combat obesity in overweight or obese patients, one should maintain a healthy diet and weight and to make smart choices about their diet (p.1, para.4-5), including reduced calorie consumption via cutting back on the number of calories eaten by eating smaller amounts of food and choosing foods lower in calories (p.4, para.1-3). Thus, the teaching of an obese human patient as in Visser et al. is also clearly a mammal who needs a decrease or reduction in appetite to maintain a healthy and/or normal weight, as evidenced by Bren, and, therefore, meets the requirement of Applicant's instantly claimed mammal in need of a decreased appetite. Moreover, while it may very well be agreed that not *all* obese or overweight mammals have an appetite that needs to be decreased (e.g., such as a patient with a genetic

abnormality that causes the obesity and not due simply to overeating), Bren still provides the factual evidence that, of all obese and/or overweight patients, there is clearly a subpopulation therein that *is in need of* a reduction in appetite to control the obese and/or overweight condition.

Fourthly, and lastly, for the record, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, as combined, clearly dictate to the contrary.

For these reasons *supra*, and those previously made of record at p.6-11 of the Office Action dated November 7, 2008, rejection of claims 1-4, 6 and 30-33 is proper.

Claims 7-9, 11 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135) and Bogentoft (WO 87/03198; 1987), further in view of The Merck Index (Monograph 792, p.121), each already of record, for the reasons of record set forth at p.11-15 of the previous Office Action dated November 7, 2008, of which said reasons are herein incorporated by reference, in view of newly cited Bren ("Losing Weight: Start by Counting Calories", *FDA Consumer Magazine*, 2002 Jan-Feb; Pub. No. FDA 04-1303C, p.1-6).

Newly amended claim 7 and newly added claim 34 (directed to substantially identical subject matter as instant claim 7 but for the fact that newly added claim 34 does not require an identification step) now require that the appetite of the obese or overweight mammal being treated needs to be decreased. The instant claims remain properly included in the present rejection because Bren teaches that, to combat obesity in overweight or obese patients, one should maintain a healthy diet and weight and to make smart choices about their diet (p.1, para.4-5), including reduced calorie consumption via cutting back on the number of calories eaten by eating smaller amounts of food and choosing foods lower in calories (p.4, para.1-3). Thus, the teaching of an obese human patient as in Visser et al. is also clearly a mammal who needs a decrease or reduction in appetite to maintain a healthy and/or normal weight, as evidenced by Bren, which meets the requirements of Applicant's instant claims.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating again that neither Phinney et al. nor Visser et al., alone or in combination, teaches or suggests each and every limitation of the claimed invention and lacks any apparent reason to combine their teachings. Applicant further asserts that Bogentoft and Merck fail to overcome these shortcomings because each reference fails to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus. Still further, Applicant alleges that Bogentoft teaches away from the instant invention because the disclosure at p.2 suggests that ingestion other than the delivery of fat directly to the ileum would not result in the food intake reduction that is seen with the method of Bogentoft, which is not needed if the instant invention is used. Applicant submits also that it would not have been obvious to combine the formulation of Phinney et al., which is used to treat symptoms of inflammatory conditions by reducing elevated levels of C-reactive protein, with Bogentoft, which uses fatty acids in an enteric preparation for treating obesity to reduce weight. Applicant again

urges that Bogentoft only discloses and enables fatty acids having up to 18 carbon atoms and, thus, fails to disclose administering an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms and alleges the Examiner has relied upon hindsight to combine the cited references.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, with regard to Applicant's continued assertions that neither Phinney et al. nor Visser et al., alone or in combination, teach or suggest each and every limitation of the claimed invention and that the rejection lacks any apparent reason to combine their teachings, Applicant is directed to p.12-17 of the Office Action dated May 23, 2008 as to why there is an apparent reason to combine the disclosures of Phinney et al. and Visser et al. and further why such a combination of references teaches and suggest each and every limitation of the claimed invention but for the concomitant use of a long-chain n-6 polyunsaturated fatty acid (which is remedied by the citations to Bogentoft and Merck). In the interest of brevity in the record, Applicant is directed thereto for such an explanation, which will not be repeated herein so as not to burden the record.

Secondly, Applicant's assertion that the cited references to Bogentoft and Merck fail to teach or suggest administering a composition with the long-chain n-3 polyunsaturated fatty acid and long-chain n-6 polyunsaturated fatty acid prior to or in conjunction with an appetite-impacting stimulus, Applicant continues to consider the references individually and not in combination as they were applied. Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside a vacuum. Applicant is also reminded that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references

without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, *as combined*, clearly dictate to the contrary.

Thirdly, Applicant alleges that Bogentoft teaches away from the instant invention. The basis of this argument is unclear. Applicant cites p.2 of Bogentoft in support of his allegation that Bogentoft teaches away from the instant invention because it suggests that ingestion other than the delivery of fat directly to the ileum would not result in the food intake reduction that is seen with the method of Bogentoft, which is not needed if the instant invention is used. However, the portion cited by Applicant is taken out of context and ignores the relevant paragraph directly following that relied upon by Applicant, wherein said paragraph states: "*This finding has been transformed into enteric preparations which are simple and convenient to use for an overweight subject*". Note, further, that Bogentoft very clearly discloses later in the reference that these enteric preparations may also be administered *orally* (see, *inter alia*, p.5, second full para.; p.1, l.1-3; p.3, second full para.; p.3, l.8-11; p.6, first full para.; p.5, last full para.; p.2, last full para.; and the paragraph bridging p.3-4), which is *not* (contrary to Applicant's assertions) a different manner of administration from that instantly claimed. This is an obvious mischaracterization of the reference and is not a point well-taken by the Examiner.

Fourthly, Applicant's allegation that there is no reason to employ the composition of Bogentoft for use with the composition of Phinney et al., which is directed for use in treating symptoms of inflammatory conditions by reducing elevated levels of C-reactive protein in patients with such elevated levels, is unpersuasive. As previously explained *supra*, the use of the tocopherol-DHA composition of Phinney et al. for the purpose of reducing C-reactive protein in conditions characterized by elevated C-reactive protein in a obese patient population that is known in the art (as evidenced by Visser et al.) to exhibit elevated C-reactive protein is clearly taught and suggested by the cited references to Phinney et al. in view of Visser et al. The concomitant use of the composition of Bogentoft would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention because the composition of

Bogentoft is effective for treating obesity and, therefore, such a person would have been motivated to combine the two therapies to (1) reduce levels of C-reactive protein that are known to be elevated in patients with obesity and (2) treat the condition of obesity (i.e., with the composition of Bogentoft) to thereby reduce the precipitating cause of elevated C-reactive protein in such obese patients. Accordingly, in view of such reasons, Applicant's allegation that there is no reason to combine the composition of Bogentoft with that of Phinney et al. is clearly without merit.

Fifthly, Applicant's assertion that Bogentoft is not properly cited prior art because the reference only discloses and enables fatty acids having up to 18 carbon atoms and, therefore, fails to disclose the administration of an amount of long-chain n-3 polyunsaturated fatty acids with 20 or more carbon atoms is unpersuasive because Bogentoft was not cited for a teaching of long-chain n-3 polyunsaturated fatty acids. This element of the claimed invention is very clearly addressed by the cited reference to Phinney et al. Rather, Bogentoft was cited for its teaching of a composition that comprises fatty acids and animal fats in the form of a triglyceride, of which arachidonic acid (i.e., the long-chain n-6 polyunsaturated fatty acid instantly claimed; see, e.g., instant claim 8) is the major constituent of animal fats. Therefore, the length of the long-chain n-3 polyunsaturated fatty acids in Bogentoft is irrelevant to the fact that the reference clearly teaches a fatty acid composition, of which it is shown that arachidonic acid is a major component (as evidenced by Merck), and, thus, clearly would have been *prima facie* obvious to one of ordinary skill in the art to combine with the composition of Phinney et al. for the reasons described *supra*.

Sixthly, and lastly, Applicant's argument that the Examiner's rationale is grounded in hindsight analysis is clearly unpersuasive. Applicant is reminded that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. However, so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Considering the fact that

the present rejection under 35 U.S.C. 103(a) relies solely on the knowledge and motivation that was generally available to one of ordinary skill in the art at the time of the invention (as clearly elucidated *supra*, as well as in each of the previous Office Actions) and does not improperly rely upon Applicant's disclosure, the assertion that the present rejection is made with impermissible hindsight reconstruction is unpersuasive.

For these reasons *supra*, and those previously made of record at p.11-15 of the Office Action dated November 7, 2008, rejection of claims 7-9, 11 and 34 is proper.

Conclusion

Rejection of claims 1-11 and 30-34 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE A. ROYDS whose telephone number is (571)272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

April 23, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614